REMARKS

Claims 1, 3, 8-14 and 20-23 are pending in this application. Claim 9 is currently amended. No new matter has been added by this amendment.

In the Office Action of August 25, 2004, the Office sets forth the following rejections:

i) claims 9-13 are rejected under 35 U.S.C. §112, second paragraph, for being indefinite as depending from a cancelled claim; and

ii) claims 1, 3, 8-14, and 20-23 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Kaswan et al. (U.S. Patent 5,639,743) in view of Carrara (U.S. Patent 5,891,462) and Merck Index (11th ed., 1989, Monograph 5103).

These rejections are respectfully traversed.

The Office rejected claims 9-13 under 35 U.S.C. §112, second paragraph for being indefinite as depending from a cancelled claim. Claim 9 has been amended. As such, reconsideration and withdrawal of this rejection is respectfully requested.

The Office rejected claims 1, 3, 8-14, and 20-23 as allegedly obvious under 35 U.S.C. §103(a) over Kaswan et al. (U.S. Patent 5,639,743) in view of Carrara (U.S. Patent 5,891,462) and Merck Index (11th ed., 1989, Monograph 5103). This rejection is respectfully traversed.

Applicant respectfully submits that the Office has not met the burden of presenting a *prima facie* case of obviousness. "It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references." *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 U.S.P.Q.2d 1626,1629 (Fed. Cir. 1996). Furthermore, the prior art must show that the inventor would have a reasonable expectation of success of achieving the present invention based on the combination of references. *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). In this instance, the Office has neither demonstrated any reason, suggestion, or motivation to lead an inventor to combine the cited references nor pointed to any prior art disclosure showing a reasonable expectation of success of achieving the present invention based on the combination of cited references. Thus, the Office has not met the burden required by 35 U.S.C. §103(a).

Kaswan et al. is directed to methods and compositions for the prevention or reversal of exocrine gland atrophy by maintaining normal physiological levels of prolactin. In contrast, the present invention is directed to a method for the treatment, prophylaxis, or reduction of the risk of developing a menopause disorder in a female mammalian subject comprising administering methyltestosterone or an enantiomer, isomer, prodrug, or salt, and estradiol or an enantiomer, isomer, prodrug or salt.

Kaswan et al. does not teach or suggest the combination of methyltestosterone and estradiol. Kaswan et al. only discloses the administration of prolactin or a compound modulating endogenous prolactin levels (e.g., cysteamine) alone or in combination with other chemicals, such as, e.g., the administration of prolactin and dihydrotestosterone (Example 4, claims 1-12) the administration of prolactin and testosterone (Claims 1-12), or the administration of prolactin and testosterone or dihydrotestosterone and estrogen (Claim 13). Kaswan et al. only discloses these combinations for the prevention or reversal of exocrine gland atrophy. Nowhere does Kaswan et al. teach or suggest the desirability of the administration of a combination of methyltestosterone and estradiol, and in fact, the disclosure of Kaswan et al. teaches away from the administration of such a combination without the concurrent administration of prolactin by requiring that the androgen "must be administered in combination with the prolactin therapy" (col. 4, lines 61-62) and by teaching that the administration involves "combined prolactin and androgen therapy" (at, for example, col. 4, line 66 and col. 7, line 63-64). As such, Kaswan does not provide either a motivation to combine or a reasonable expectation of success for a method for the treatment, prophylaxis, or reduction of the risk of developing a menopause disorder in a female mammalian subject comprising administering methyltestosterone or an enantiomer, isomer, prodrug, or salt, and estradiol or an enantiomer, isomer, prodrug or salt, as provided by the present invention.

Carrara (U.S. Patent 5,891,462) does not cure the defects of Kaswan et al. discussed above. Carrara is directed to a gel composition comprising estradiol or norethindrone acetate, a fatty alcohol, a monoalkyl ether of diethylene glycol, an alkanol, and a polyalcohol. Nowhere in Carrara is there a teaching, suggestion, or incentive to combine methyltestosterone and estradiol as in the present invention.

The Merck Index does not teach or suggest the combination of methyltestosterone and estradiol as in the present invention. The Examiner has failed to point to any teaching,

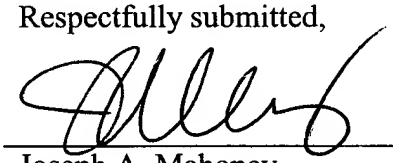
suggestion, or incentive in the Merck Index to combine methyltestosterone and estradiol to treat female menopausal disorders or to combine isopropyl myristate in the gel of Carrara.

As set forth above, neither the combination of Kaswan et al. with Carrara and Merck, nor any of the references individually, teach or suggests the present invention. Thus, reconsideration and withdrawal of the rejection of claims 1, 3, 8-14, and 20-23 as allegedly obvious under 35 U.S.C. § 103(a) over Kaswan et al. in view of Carrara and the Merck Index is respectfully requested.

With entry of the above Amendment and in view of the foregoing Remarks, Applicant respectfully submits that the application is in condition for allowance and requests that a timely Notice of Allowance be issued in this application. None of Applicant's amendments are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application. If, in the opinion of the Examiner, a phone call may help to expedite prosecution of this application, the Examiner is invited to call Applicant's undersigned attorney at (312) 701-8979.

Dated: February 24, 2005

Respectfully submitted,



Joseph A. Mahoney
Reg. No. 38,956

CUSTOMER NUMBER 26565
MAYER, BROWN, ROWE & MAW LLP
P.O. Box 2828
Chicago, IL 60690-2828
Telephone: (312) 701-8979
Facsimile: (312) 706-9000